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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,202	06/24/2003	Andrew D. Firlik	33734-8046US	4373

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EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,202	FIRLIK ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/19/05 & 1/25/06*. & 2/17/06 & 4/21/06 & 4/10/06 & 5/16/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 30-44 have been considered but are moot in view of the new ground(s) of rejection. As presented below claims 30-46 are rejected in view of John (US 6,066,163), Firlik et al. (US Patent Publication 20050021105 A1) and Naritoku et al. (US 6,556,868 B2).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 include an improper Markush group.

> A Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

The examiner recommends changing "selecting the behavioral therapy to include at least one of" to –selecting the behavior therapy to include at least one selected from the group constituting of--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 30-36 and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by John (US 6,066,163). John disclosed an adaptive brain stimulation that aids in rehabilitation of patients suffering from traumatic brain injury, coma and other brain dysfunction.

As to claims 30 and 36, "a present state of a patient can be divided into a "stimulation period" and a "post-stimulus period." The stimulation period is defined as a period that is in, or is temporally close to, the period in which stimulation occurs, for example from stimulation onset until stimulation offset or lasting up to, for example, 1 second post-stimulus 62c. The stimulation period may also be sub-divided into two or more smaller sections of interest 62a, 62b. The "post-stimulus period" may similarly be a single period or may be divided into two or more sub-periods 62c, 62d, 62e which begin after the stimulation period and last until the next stimulation period. The post-stimulus period may be characterized by complete cessation of stimulation or by a relatively decreased level of stimulation compared to the stimulator state." (col. 6, lines 54-67). John describes the post-stimulus lasting until the next stimulation period, which is indicative "of a therapy period that includes at least one session", as claimed by Applicant.

As to claims 31-32, "the brainstem auditory evoked potential (BAEP) and somatosensory evoked potential (SSEP) are considered valuable diagnostic means to

determine the probability that a patient will successfully recover from coma and regain consciousness. By defining a present state, estimated by qualifying the BAEP, SSEP, EEG or EMG during the post-stimulus period, and comparing it to an appropriate reference state, the clinical efficacy of a set of parameters for peripheral stimuli can be evaluated and changed if necessary to aid in recovery of patients from coma"(col. 14, lines 53-62). Once the patient has achieved successfully recovery from a coma, the electrical stimulation would no longer be required. Thus, stimulation is ceased when a "predetermined level of functional recovery" is achieved, as claimed by Applicant.

As to claim 33, "appropriate sites of activation can be determined by functional and structural imaging technology such as PET, FMRI, SPECT, EEG, EP, MEG, and by pharmacological testing such as assays of CSF fluid metabolite levels"(col. 5, lines 43-47).

As to claim 34, the direct brain stimulator (DBS) 50 is depicted in figure 1. "DBS's can consist of implanted electrodes or stimulating devices"(col. 12, lines 55-56).

As to claims 35 and 39-41, "the ABS system and method also contains devices for auditory stimulation such as headphones 56a, for visual stimulation such as LED goggles 56b, and for somatosensory stimulation such as a tactile stimulator 56c that is attached to the wrist or fingers of the subject, all of which are controlled and powered by the PC. These stimulation device enable the generation of auditory, visual, and somatosensory transient evoked potentials and steady state potentials that can be recorded from the EEG electrodes"(col. 5, lines 15-23).

The therapy that includes the use of LED goggles for visual stimulation elicits a visual stimulus, and thus is a visual task. Also, tactile stimulation would naturally be "intentional use of an affected body part" as claimed by the Applicant, as well as part of the "activities of daily living".

As to claim 38, "in addition to the previously described types of direct electrical brain stimulation, stimulation of all five senses, both separately and in combination, has been shown to be effective in decreasing the time spent in coma (Sosnowski C, et al. Early intervention: coma stimulation in the intensive care unit. J Neurosci Nurs. 1994 December; 26(6): 336-341; Mitchell S, et al. Coma arousal procedure: a therapeutic intervention in the treatment of head injury. Brain Inj. 1990 July; 4(3): 273-279. Wood R L, et al. Evaluating sensory regulation as a method to improve awareness in patients with altered states of consciousness: a pilot study. Brain Inj. 1992 September; 6(5): 411-418.)" (col. 14, lines 32-43). Therefore, sensory stimulation affects awareness and thus provides cognitive therapy.

2. Claims 30-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Firlik et al. (US Patent Publication 20050021105 A1). Firlik et al. discloses an apparatus for affecting a change in neural function by electrical stimulating the brain at a location where neuroplastic changes occur.

As to claim 30, "several embodiments of methods for enhancing neural activity in accordance with the invention are expected to provide results that create, promote or prolong the desired neural-function even after terminating the stimulation"(page 6,

paragraph 74). Therefore, the stimulation treatment is given in at least one therapy session during a therapy period.

As to claims 35-44, "figure 4B is a table illustrating a first list containing a plurality of conditions that affect physical and/or cognitive functions, and a second list containing a plurality of anatomic locations where neural-activity is suspected to occur for carrying out the particular functions. For example, if a patient has experienced a stroke at the primary motor cortex in the frontal lobe, the stimulation site where neuroplasticity is suspected to be occurring, or expected to occur in the future, is in the pre-motor cortex and/or the supplementary motor cortex anterior to the stroke in the frontal lobe. In another particular embodiment of the method 100a for treating expressive language disorders, the stimulation site is located at Broca's area of the inferior frontal lobe of the cortex. In still another embodiment of the method 100a for treating language comprehension disorders, the stimulation site is located at Wernick's area of the parietal lobe of the cortex. Referring to FIG. 4B still, the method 100a can also be practiced for treating learning and memory disorders by selecting a stimulation site at the medial temporal lobe of the cortex. Additionally, another embodiment of the method 100a includes treating mood disorders by selecting a stimulation site at a limbic system component"(page 7, paragraph 84).

As to claim 45-46, "the actual electrical potential applied to electrodes implanted in the brain to achieve a subthreshold potential stimulation will vary according to the individual patient, the type of therapy, the type of electrodes, and other factors"(page 9, paragraph 96).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

3. Claims 30-32, 34-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Naritoku et al. (US 6,556,868 B2). Naritoku et al. discloses improved learning or memory by vagus nerve stimulation

Naritoku et al. discloses in col. 7, lines 29-39, that "stimulation of the vagus nerve results in the activation of a variety of processes in the brain that result in changes in brain function. It is likely that only some of these processes are related to the modulation of memory storage and that this stimulation also modulates other changes or plastic processes in the brain as well. That directs vagus nerve stimulation nfluences plastic processes related to brain development or the recovery of function from brain injury is a very good possibility given the already demonstrated effect on one major form of neural plasticity, i.e., memory storage".

Naritoku et al. further discloses in col. 12, lines 37-61, "the present invention is directed to a method of treating a human or animal subject suffering from a symptom selected from the group consisting of memory impairment, a learning disorder, impairment of cognitive processing speed, impairment of acquisition of perceptual skills, impairment of acquisition of motor skills, and impairment of perceptual processing. The

method comprises selecting a human or animal subject suffering from a symptom selected from the group consisting of memory impairment, a learning disorder, impairment of cognitive processing speed, impairment of acquisition of perceptual skills, impairment of acquisition of motor skills, and impairment of perceptual processing; and applying a stimulating electrical signal to the vagus nerve of the human or animal subject. The electrical signal is characterized as being effective to alleviate the symptom in the human or animal subject. The method further comprises monitoring the human or animal subject via a method selected from the group consisting of a clinical test, a laboratory test, determination of clinical outcome, and combinations thereof, to determine if the symptom has been alleviated, or if further stimulation of the vagus nerve is required to alleviate the symptom; and if required, further stimulating the vagus nerve and monitoring the human or animal subject as in the preceding steps, until the symptom has been alleviated". The examiner considers learning to incorporate reading, and as such a reading task is also part of a learning task.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 45-46 are rejected under 35 U.S.C. 102(e) as anticipated by John (US 6,066,163) or, in the alternative, under 35 U.S.C. 103(a) as obvious over John (US 6,066,163) in view of Collins (US 5,782,873).

As to claims 45-46, John discloses "both electrical and pharmacological stimulation can be used together to further improve the patients condition. In one application, infusion of a substance intrinsically excitatory to a particular region is made contingent upon a specific pattern of cellular firing or upon an increase of a specific frequency in the EEG. Local administration of a neurotransmitter contingent upon a particular firing pattern increases the chances for subsequent repetition of this pattern. Thus, linking the infusion of a region-appropriate substance such as norepinephrine into the reticular region to a state of increased excitability should facilitate the probability of an increase in increase in subsequent firing rates"(col. 13, lines 14-25). The infusion of a intrinsically excitatory substance will provide low threshold stimulation that cause a region to be in an increased excitability and enables an increase in subsequent firing.

In the alternative, John discloses the device substantially as claimed but fails to teach delivery of stimulation below a threshold level for neurons at the stimulation site. Collins teaches that it is known to input sub-threshold stimulus to the sensory cell area for the purpose of effectively lowering the threshold of the sensory cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the stimulation signal as taught by John with the sub-threshold stimulation signal as taught by Collins, in order to effectively lower the threshold of the sensory cells to facilitate enhancement in healthy individuals and treatment for those

whose sensory system is degraded by disease, such as peripheral neuropathies or strokes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alyssa M Alter
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Art Unit 3762

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